UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 10, 2011

MEMORANDUM

Subject: Efficacy Review for Sanidate 5.0; EPA Reg. # 70299-19; DP Barcode: D383969

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1/24/11

To: Marshall Swindell PM 33/ Abigail Downs
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Applicant: BioSafe Systems, LLC
22 Meadow Street`
East Hartford, CT 06108

Formulation from the Label:

Active Ingredient	% by wt.
Hydrogen peroxide	23.0 %
Peroxyacetic Acid	5.3 %
Other Ingredients:	71.7 %
Total	100.0 %

I. BACKGROUND

The product, SaniDate 5.0 (EPA Reg. # 70299-19), is an EPA-approved disinfectant (bactericide, fungicide, virucide) with sanitizing and fungicidal effects, for use on hard, non-porous surfaces in institutional, commercial, industrial, food processing, animal care, and hospital or medical environments. The applicant requested to register the product for use as a sanitizing rinse but previously submitted data were not reviewed. The label states that the product is effective as a disinfectant on lightly soiled surfaces. Studies were conducted at BioScience Laboratories, Inc., located at N. Willson Avenue in Bozeman, MT 59715.

This data package contained one study (MRID 479153-04), Statements of No Data Confidentiality Claims for the study, and the proposed label.

II. USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces. The product may be used to treat hard, non-porous surfaces such as appliances, barber/salon tools, bathroom fixtures, bed frames, benches, beverage dispensing equipment, bins, boxing and packing equipment, brooms, buckets, cabinets, cages, cans, carts, chairs, coolers, conveyors, corers, counter tops, crates, drains, evaporators, fan blades, filter housings, filters, floors, garbage cans/bins/pails, hooks, kennel runs, mops, pails, pans, pasteurizers, peelers, personal protective equipment, piping, platters, processing equipment, pumps, racks, rakes, scrapers, shelves, shovels, sinks, squeegees, tables, tanks, tools and equipment, trays, valves, vats, vehicles, walls, walkways, water transfer and handling systems. The proposed label indicates that the product may be used on hard, non-porous surfaces including: Formica, glass, glazed porcelain, glazed tile, linoleum, metal (e.g., aluminum, stainless steel, steel), plastic (e.g., CPVC, nylon, polyethylene, polyvinylchloride, vinyl), sealed fiberglass, and sealed wood. Directions on the proposed label provide the following information regarding preparation and use of the product:

> As a sanitizer on food contact surfaces: Remove gross food particulate matter and soil by a warm water flush, pre-flush, pre-scrape, or pre-soak. Thoroughly wash surfaces or equipment with a good detergent or compatible cleaning solution. Do not rinse. Prepare a use solution by adding 1.6 fluid ounces of product to 5 gallons of potable water (a 1:400 use solution). Apply by wiping, mopping, or coarse spray, or by adding to a closed system. Allow a contact time of 1 minute. Drain thoroughly. Do not rinse.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces): Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at

the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x 10^6/mL for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution for the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 479153-04 "An Evaluation of the Bactericidal Efficacy of one Test Formulation for Use as a Sanitizing Rinse on Previously Cleaned Food-Contact Surfaces." Test Organisms: *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538), for SaniDate 5.0, by Terri Eastman. Study conducted at BioScience Laboratories, Inc. Study completion date – October 27, 2009. Amended report date – November 11, 2009. Laboratory Study Number 090812-204.

This confirmatory study was conducted against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538). One lot (Lot No. 09141-1) of the product, SaniDate 5.0, was tested using BioScience Laboratories protocol # 090812-204 (copy provided). The protocol referenced the AOAC Germicidal and Detergent Sanitizing Action of Disinfectant (# 960.09) and US EPA Pesticide Assessment Guidelines, Subdivision G, Product Performance (November 1982). The product lot tested was at least 60 days old at the time of testing. A use solution was prepared by adding 1.0 mL of the product and 399 mL of 400±20 ppm AOAC synthetic hard water (titration results not provided; a 1:400 dilution). A 99-ml aliquot of the prepared use solution was transferred to each of two 250 ml Erlenmeyer flasks. The flasks were placed in a 25±1°C water bath for at least 20 minutes. One-ml bacterial suspension (adjusted to ~1x10^{10} CFU/ml) was added to each flask. One-ml aliquots of the bacterium-test solution were transferred to 9 ml of Butterfield's Phosphate Buffer Solution with product neutralizers, including 0.1% sodium thiosulfate and Catalase 30 seconds after the addition of the bacterial suspension; vortex mixed to suspend the surviving organisms. One mL and 0.1 mL aliquots were plated in quadruplicate. All subcultures were incubated for 63.75 hours at 35±2°C prior to examination. Following incubation, the subcultures were counted manually. Controls included those for carrier population, purity, sterility, and neutralizer efficacy verification. The reported average number control population recovery, expressed in colony forming units per ml, for each test microorganism, are as follows: ***Escherichia coli* 1.985 x 10^8** and ***Staphylococcus aureus* 1.7775 x 10^8**.

V. RESULTS

MRID Number	Organism	Replicate	Average No. Surviving (CFU/mL)	# Control Recovery (CFU/mL)	Percent Reduction
479153-04	*Escherichia coli* (ATCC 11229)	1	$<1 \times 10^1$	1.985×10^8	>99.999
		2	$<1 \times 10^1$	1.985×10^8	>99.999
	Staphylococcus aureus (ATCC 6538)	1	$<1 \times 10^1$	1.7775×10^8	>99.999
		2	$<1 \times 10^1$	1.7775×10^8	>99.999

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 479153-04) support the use of a 1:400 dilution of the **tested product lot of SaniDate 5.0**, as a sanitizing rinse against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 30-second contact time. Bacterial reductions of at least 99.999 percent over the parallel control were observed within 30 seconds. Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth

VII. LABEL

The product SaniDate 5.0 (EPA Reg. # 70299-19) is a me-too product of SaniDate 5.0 Sanitizer (EPA Reg. # 70299-11) which failed ATP. This product should not be registered until SaniDate 5.0 Sanitizer (EPA Reg. # 70299-11) ATP problem is solved.

Registrant must test their product at the lower certified limit [16% Hydrogen Peroxide and 4.2% Peroxiacetic acid for SaniDate 5.0 Sanitizer (EPA Reg. # 70299-11) and SaniDate 5.0 (EPA Reg. # 70299-19)]. **It is unknown if all tested product lots were formulated at the lower certified limits**. Product lots were not assayed for their content of active ingredients at the time of testing. Data reports had nominal concentrations of 23% and 5.3% in parentheses.

As it is, we assume that product lots were at nominal concentrations at the time of testing. The acceptable testing dilutions should range from **1:505 to 1:575** for label claims of 1:400 dilution, and **1:323 to 1:368** for label claims of 1:256 dilution.

1. After ATP problem is solved and tested product lots formulation to the lower certified limits confirmed, the proposed label claims that a 1:400 dilution of the product, SaniDate 5.0, is an effective sanitizer against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces for a 1-minute contact time:

Escherichia coli
Staphylococcus aureus
Escherichia coli O157:H7
Pediococcus damnosus
Lactobacillus malefermentans
Saccharomyces cerevisiae

These claims will be are acceptable, as they are supported by provided confirmatory data for *Escherichia coli* and *Staphylococcus aureus*.

2. ATCC designation numbers are required in one of the following locations:

   - on the data matrix;
   - on the master label (as optional text) with the listing of the organisms claimed; or
   - as the final page of the master label (as optional text).